

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: |) Confirmation No.: 4282 |
|-----------------------------|---------------------------|
| Kenshi KAMEI et al |) Art Unit: 1614) |
| Appln. No.: 10/532,585 |) Examiner: P.G. Spivack |
| Filing Date: April 25, 2995 |) April 16, 2007 |
| For: THERAPEUTIC AND/OR |) ATTY.'S DOCKET: KAMEI=2 |

REPLY: REQUEST FOR RECONSIDERATION

Customer Service Window, Mail Stop AF Honorable Commissioner for Patents U.S. Patent and Trademark Office Randolph Building, 401 Dulany Street Alexandria, Virginia 22314

Sir:

The applicants are in receipt of the **final** Office Action mailed December 26, 2006, which has been carefully studied. Attached is a petition for one month's extension of time and payment of the one month's late fee.

The claims in the application remain as claims 10 and 15-19, and these claims define novel and unobvious subject matter under Sections 102 and 103, whereby allowance is warranted. The prior art does NOT disclose applicants' compound. Favorable reconsideration and allowance are earnestly solicited.

Claims 10 and 15-19 have been rejected under Section 102(e) as being anticipated by Ashley et al, USP 6,562,795 ("Ashley"). This rejection is respectfully traversed.

The rejection states that Ashley discloses applicants' compound GM-611 used to treat chronic constipation, but it is not correct that Ashley discloses applicants' compound. Instead, there are a number of structural differences between the closest compound of Ashley (which, according to the rejection is the compound of claim 4 wherein R^1 is hydroxyl, R_3 is isopropyl, R_6 is methoxy and R_8 is ethyl) and applicants' compound GM-611.

To point out structural differences at two locations, below please find a comparison of the structural formulas of the two compounds, the aforementioned compound of Ashley being on the left and GM-611 being on the right, and in which an ellipse is added at two different locations where structural differences between the two compounds appear.

Compound of Claim 4 in U.S. Patent 6,562,795

GM-611

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Structural differences are as follows:

- (1) The Ashley compound has a double bond between carbon atoms the 6- and 7-positions, while GM-611 has a single bond at the corresponding site.
- (2) GM-611 has a methyl group at the 6-position, while the Ashley compound does not.
- (3) The Ashley compound has an an hydroxy group at the 11-position, whereas GM-611 has an oxo group at the same site.

Accordingly, Ashley does not disclose GM-611 and thus the use of GM-611 as claimed for any purpose, and therefore does not disclose that GM-611 has a pharmacological effect to accelerate normal defecation and consequently is useful for treating constipation.

Withdrawal of the rejection is in order and is respectfully requested.

Applicants note for the record that all the other prior art documents of record, including newly cited Clark et al, are apparently deemed by the PTO to be insufficiently material to warrant application against any of applicants' claims.

Applicants believe that all issues raised in the final action are addressed above in a manner that should lead

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to early formal allowance of the present application.

Accordingly, applicants respectfully request favorable consideration and early formal allowance.

Respectfully submitted,

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